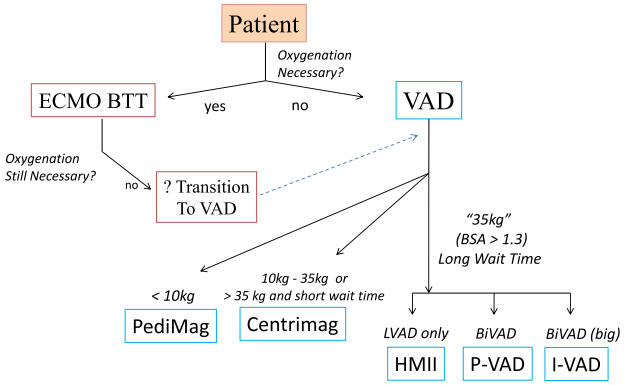

FIGURE 3. Our general approach to mechanical ventricular assistance. *ECMO,* Extracorporeal oxygenation; *BTT,* bridge to transplantation; *VAD,* ventricular assist device; *P-VAD,* paracorporeal ventricular assist device; *I-VAD,* implantable ventricular assist device; *BSA,* body surface area.

prime and elimination of bridges, connectors, and diamonds has reduced some of the morbidity experienced with the earlier circuit.

In summary, we have found it helpful to have a variety of mechanical ventricular assistance available so as to tailor the device strategy to the patient. Although we have no firm algorithm in this setting, our general approach is outlined in Figure 3. Our initial indication for ECMO use pertains to the need for oxygenation, and we favor VAD support where feasible, given (1) the substantial advantages of potential extubation and ambulation/rehabilitation and (2) the disadvantages of having an oxygenator in line (eg, activation of inflammation, increased requirement for anticoagulation, and limited durability). This inclination is in keeping with other reports demonstrating superior survival in patients supported with VAD rather than ECMO.[18,19] The selection of VAD devices is directed mostly by size and the need for univentricular or biventricular support; however, the optimal strategy to support patients in the "gray zone" of size (15-35 kg) remains somewhat patient-specific. For those patients in whom neurologic status is in question, we have used a "bridge to decision" approach, initially using a temporary device or ECMO until a more definitive neurologic prognosis can be determined, at which point transition to a longer-term device can take place. Although we have favored using ECMO to support patients with complex congenital heart disease in the past, we would imagine them to be VAD candidates (following this algorithm by size) in many circumstances.

Mechanical circulatory support using a variety of devices is a highly effective means of both bridging patients to transplantation and supporting patients after transplantation during hemodynamic crises. The more widespread availability of smaller and potentially implantable devices for children will only serve to improve these strategies, while potentially affecting favorably the substantial morbidity related to anticoagulation in the smallest patients.

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Discussion

Dr J. William Gaynor *(Philadelphia, Pa).* I congratulate Dr Chen and his co–investigators on a very interesting presentation and thank them for allowing me to review the manuscript.

This is an important subject. As we have all seen, increasing numbers of children are listed for cardiac transplantation. In light of the nonincreasing donor pool, waiting times continue to increase and the potential loss of patients on the waiting list is a significant problem. The findings of this study are very similar to our findings in a similar sized patient cohort, that overall survival to transplant is excellent and that survival after transplant from a VAD is equivalent to that of patients undergoing transplantation without a VAD. I think this is a very effective technique.

We also see the same problems with thrombosis and hemorrhage, particularly in the very small devices and in the very small EXCOR devices, so our overall outcomes are very similar. We do have some management differences, and that is going to be the focus of my question.

We rarely need to use BiVAD support. We have a very similar patient mix and primarily cardiomyopathies, and in 33 patients we have only needed to use BiVAD support twice. We place an LVAD in the operating room, attempt to wean from bypass, usually with inhaled nitric oxide, and if we do not require excessive inotropic support, we have been very successful and continue with that.

What are your criteria for a BiVAD? How do you decide? Are you continuing to use a lot of BiVAD support?

Dr Chen. Thank you. Excellent question. Our management is very similar to yours insofar as we would always like to try to get away with one pump only, if only because more pumps just mean more potential for complications.

Earlier in our series we were seeing more children who were really in shock and going to the operating room while undergoing chest compressions. Those children are the least likely to come away with a single-sided device only. As we have gotten more comfortable and more aggressive, the likelihood of catching patients earlier who will have reasonable right ventricular function is good.

I also think that in the later part of this experience we were using many fewer pulsatile, fill-to-empty left ventricular inflow devices. None of these, the centrifugal or axial flow devices, decompresses the ventricle quite as much and probably causes as much septal shift. So more recently I am hoping, as you point out, that we will be using fewer and fewer BiVADS and more and more LVADs as long we can effectively manage some right heart failure medically.

Dr Gaynor. You also mentioned that you switched to atrial cannulation. We have continued to use primarily apical cannulation except in patients with restricted physiology, and we believe that we get better decompression of the ventricle. We have not seen major problems with the septal shifting. When would you use atrial cannulation now, if ever?

Dr Chen. That is a relatively new finding for us. It has been prompted a little bit by the hemorrhage/thrombosis component, which is that putting in the 2 atrial cannulas is very easy off pump. With this strategy, you can get away with half-dose heparin and the bleeding is trivial in the operating room.

The disadvantage, of course, is that the decompression of the ventricle is less effective. Also, there is a possibility that if the aortic valve does not open, these children will have stasis in the left ventricle and later clot if we do not start fairly aggressive anticoagulation quickly enough. Some of the devices, of course, cannot be inserted atrially, but it is a much simpler approach if it is possible.

Dr Gaynor. I have 1 final question from the manuscript, which you did not address in the presentation, concerning the management of patients who have intracardiac shunts. We always do a very careful search for intracardiac shunts, and we have enclosed them if we know we have them. We had 1 patient with an undiagnosed patent foramen ovale who was significantly desaturated when he came off LVAD support. You mentioned in the manuscript that with this off–pump technique you will leave patients with intracardiac shunts and have not seen that problem. Could you expand on that?

Dr Chen. It was really more out of good luck, I think, than anything. Regarding the intracardiac shunt component, a lot of these newer continuous flow devices do not decompress the ventricle enough that we get as much right-to-left shunting as we used to with their fill-to-empty predecessors. I was very concerned in 1 patient, the smallest patient here, who had a BiVAD and multiple ventricular septal defects, that it was going to be hard to control the degree of shunting. However, it ended up not being so much of a problem. Atrial cannulation can be tricky with regard to atrial communications, though, and I suspect those probably still need to be closed.

Dr Gaynor. This answer brings up a further question. Most of our cases are bridged to transplant; we almost never bridge to recovery. We are always concerned that children frequently come in with high left atrial pressures and pulmonary edema, and we are concerned about dropping that left atrial pressure to improve the lungs. If you are using a device that does not decompress, will the atrial cannulation alone drop the left atrial pressure sufficiently to allow the lungs to recover?

Dr Chen. I do not know the answer to that. I would assume that the atrial cannulation probably will. I certainly do not think ECMO does though. It has definitely been our policy that if you are bridging to transplant with ECMO and you suspect high atrial pressures, you have to go to the catheterization laboratory for a septostomy at the time of instituting ECMO support, or very soon thereafter.

Dr Carl L. Backer *(Chicago, Ill).* For the patients whom you are supporting with ECMO, what is your decision tree for where to do the cannulation—neck, femoral, or median sternotomy? We recently had an older child who came in with myocarditis. I put her on ECMO through the chest and she came off ECMO and went home after she was treated. The advantage of this in the older child is that there are no femoral or neck vessel complications. When these patients come in, it seems that there is always some discussion about where to do the ECMO cannulation. What is your strategy?

Dr Chen. For the smaller children—and our cutoff ends up being about 2 years—we go on through the neck. The hard group is that between about 5 kg and about 15 kg, because we have had a fair number of groin complications with that size range, even with the T'd-off sidearm that goes through the dorsalis pedis. When the patients get to be older and bigger, you can easily go with 2 venous cannulas, neck and groin, and femoral artery. It is just that middle group, I think, that is probably the right group to be having a sternotomy because it is much simpler and the vascular complications are substantial.

Dr Hajime Ichikawa *(Osaka, Japan).* I am really interested in your atrial cannula. We used to use an atrial cannula with Japanese Toyobo LVADs and we had a lot of problem with thrombosis.

Do you change the anticoagulant regimen when using an atrial cannula?

Dr Chen. May I ask a question? Is the thrombosis in the pump or in the ventricle?

Dr Ichikawa. In the ventricle.

Dr Chen. We have worried a lot about thrombosis in the ventricle. We definitely run PTTs pretty high on all of these children; especially in the smaller children, we will run the PTTs well above 100. This is not necessarily based on the flow in the ventricle and so forth, but just as a general policy.

Dr Shunji Sano *(Okayama, Japan).* When I look at your table, the average duration is relatively short compared with the Toyobo device. The Toyobo device is completely different, almost 1 year. But most of these patients are relatively large children. So even with a Toyobo device, you use the adult size device. Why is the duration long and why was there only 1 episode of thromboembolism?

When I look at the small child, in this case comprising only 3 patients—1 with a Berlin Heart, 1 with the PediMag, and 1 with the Abiomed—they weighed less than 10 kg. The longest duration was 17 days. How long do you think it is safe to wait for transplant with these 3 devices in very small babies weighing less than 10 kg—1 month or 6 months or 1 year?

Dr Chen. The answer as to why that waiting time was so long for the Toyobo patients is that, as you know, children in Japan have to wait a fair amount of time for a potential donor. Each US program can only have 5% of their transplant volume as comprised of foreign national candidates, so sometimes these international children have to wait for the calendar year to turn over before we can accept them. There can be quite a bit of time for waiting and it takes time to raise money and so forth.

Early in our experience we used the adult CentriMag circuit rather than the PediMag; that is a 3/8–inch connection all the way around. It is actually a fairly large priming volume. A lot of children who were just over 10 kg in this group, about 11 to 13 kg, would form a lot of early thrombus in the tubing, and so I started adapting to exchanging the tubing routinely at 2 weeks. We carried some of those patients up to about 6 weeks.

I do worry, though, when we put the smallest children on devices. We really try to get the transplant done as quickly as possible. The good news is that most of them can receive transplants across ABO blood groups because of their age.